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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,650	02/12/2001	Robert John D'Amato	43170-253692 (05213-0493)	2466

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/780,650	D'AMATO ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 26-32,34 and 36-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 26-32,34 and 36-40 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/05;9/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on September 29, 2004 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

3. Claim 34 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30, 32, 33, 35, 36, 38, 39 and 41 of copending Application No. 10/077,142. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass treating ocular angiogenesis utilizing 2-methoxyestradiol. Unlike, the above-cited copending application, the present application is limited to the utilization of 2-methoxyestradiol. However, the genus recited by copending Application No.

10/077,142 encompasses 2-methoxyestradiol (see claims 35 and 36 of copending Application No. 10/077,142). In addition, the specific diseases recited by the instant claim are included in the definition of "ocular angiogenic diseases" (see page 3, lines 15-18 of the present specification). Therefore, it would have been obvious to the skilled artisan at the time of the present invention to utilize 2-methoxyestradiol in the treatment trachoma, retinopathy of prematurity etc. as recited by the present application with the reasonable expectation of treating ocular angiogenesis as recited by copending Application No. 10/077,142.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Note: Application No. 10/077,142 was allowed on November 1, 2004.

4. Claims 26-32, 34 and 36-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-46 of copending Application No. 10/617,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass treatment of various disorders such as atherosclerosis and tumors comprising the administration of 2-methoxyestradiol. The instant application differs from the above-mentioned copending application in that it is limited to a single compound, i.e., 2-methoxyestradiol. However, the copending application discloses 2-methoxyestradiol (see the entire disclosure of Application No. 10/617,150 especially page 11, example 1 and pages 13-14, Tables 1 and 2). Thus, it would have been obvious to the skilled

artisan in the art to utilize 2-methoxyestradiol as recited by the present application in treatment of the various disorders as recited by both applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 27, 28 and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/918,627. Although the conflicting claims are not identical, they are not patentably distinct from each other because both encompass treating cancer comprising the administration of 2-methoxyestradiol. The instant application differs from the above-mentioned copending application in that it is limited to a single compound, i.e., 2-methoxyestradiol. However, the copending application discloses 2-methoxyestradiol (see the entire disclosure of Application No. 10/918,627 especially page 11, example 1 and pages 13-14, Tables 1 and 2). Thus, it would have been obvious to the skilled artisan in the art to utilize 2-methoxyestradiol as recited by the present application in treatment of cancer as recited by both applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 26-32, 34 and 36-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 13 and 24 of copending Application No. 10/379,991. Although the conflicting claims are

not identical, they are not patentably distinct from each other because they both encompass treating diseases characterized by abnormal cell mitosis such as atherosclerosis, tumors, etc. comprising the administration of 2-methoxyestradiol. The instant application differs from the above-mentioned copending application in that it is limited to a single compound, i.e., 2-methoxyestradiol. However, the copending application discloses 2-methoxyestradiol (see the entire disclosure of Application No. 10/379,991 especially page 11, example 1 and pages 13-14, Tables 1 and 2). Thus, it would have been obvious to the skilled artisan in the art to utilize 2-methoxyestradiol as recited by the present application in treatment of diseases such as atherosclerosis, tumors etc. characterized by abnormal cell mitosis (see page 3, lines 6-23 of Application No. 10/379,991).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 26, 27, 29-32, 34 and 36-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46-52 and 59-66 of copending Application No. 10/280,831. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass the treatment of various diseases such as atherosclerosis, tumor metastasis, benign tumors etc. utilizing 2-methoxyestradiol. The difference between the two applications is in the recitation of the diseases treated. However, each of the disorder recited by the instant claims is recited by claim 46 of

copending Application No. 10/280,831. Thus, the utilization of 2-methoxyestradiol in treatment of atherosclerosis(claim 26), benign tumors (claim 29) etc. as recited by the present application would have been obvious based on claim 46 of the above-cited copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Note: Application No. 10/280,831 was allowed on December 22, 2004.

8. Claims 26-32, 34 and 36-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-46 of copending Application No. 10/789,471. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass treatment of various disorders by inhibiting neovascularization comprising the administration of 2-methoxyestradiol. The instant application differs from the above-mentioned copending application in that it is limited to a single compound, i.e., 2-methoxyestradiol. However, the copending application discloses 2-methoxyestradiol (see the entire disclosure of Application No. 10/789,471 especially page 3, lines 9-22; page 10, lines 7-18; page 13, example 1 and pages 15-16, Tables 1 and 2). Thus, it would have been obvious to the skilled artisan in the art to utilize 2-methoxyestradiol as recited by the present application in inhibiting neovascularization as encompassed by both applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seegers et al.

Seegers et al. teach the antimitotic effect of 2-methoxyestradiol in MCF-7 and HeLa cell lines (see the entire article, especially Abstract and pages 807-809, Discussion).

The instant claims differ from the reference by reciting the treatment of human or animal. However, it is routine in the medical art to extrapolate the effect of a compound from in vitro studies to in vivo use. Therefore, the skilled artisan would have the reasonable expectation that 2-methoxyestradiol would be antimitotic when administered in vivo and, thus, would be useful in treatment of solid tumors such as breast and cervical cancers. The motivation would be based on the teaching of the antimitotic effect of 2-methoxyestradiol in MCF-7 and HeLa cells as taught by Seegers et al.

Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
May 10, 2005